

REMARKS

Claims 1-18 remain pending in this application. Claims 10 and 11 have been allowed.

I. § 102 and § 103 REJECTIONS

Reconsideration of pending claims 1-9 and 12-18 of the subject application is requested.

Applicant submits that the pending claims are not anticipated or made obvious by U.S. Patent No. 4,696,946 to Green et al. (Green). Each element of the pending claims is not disclosed by Green, as required to create a case of anticipation. Furthermore, a *prima facie* case of obviousness for rejecting pending claims 1-9 and 12-18 has not been established. The Patent and Trademark Office's burden of establishing a *prima facie* case of obviousness is not met unless "the teachings from the prior art itself would appear to have suggested the claimed subject matter to a person of ordinary skill in the art." In re Bell, U.S.P.Q. 2d 1529, 1531 (Fed. Cir. 1993) (quoting In re Rinehart, 189 U.S.P.Q. 143, 147 (C.C.P.A. 1976)). Green does not suggest all the elements of the pending claims. Thus, Applicant submits that a *prima facie* case of obviousness for rejecting the pending claims is not established with this reference.

Green does not disclose or suggest a formulation containing both sodium hydroxide and calcium hydroxide, as claimed by Applicant. While Green discloses that sodium hydroxide or calcium hydroxide may be used to create an acceptable salt from particular chemical compounds for treating psoriasis, it does not disclose or suggest using sodium hydroxide and calcium hydroxide in combination. Further, Green teaches that the salt created by using sodium hydroxide or calcium hydroxide is then used in making a formulation for treating psoriasis. Green does not suggest putting sodium hydroxide or calcium hydroxide in the treatment formulation, as claimed by Applicant. Furthermore, Green does not teach that an active

ingredient could be delivered through one's nail using a dual component penetration system of calcium hydroxide and sodium hydroxide. This is important because it is this dual combination that allows Applicant's antifungal agent to penetrate the nail to treat fungus beneath the nail.

Further, nothing in the cited reference suggests the desirability of putting an antifungal agent into a dual component penetration system of sodium hydroxide and calcium hydroxide. In fact, Green provides no teaching or suggestion that an antifungal agent would even be compatible with a mixture of sodium hydroxide and calcium hydroxide.

In addition, the active ingredient of Green's formulation is useful for treating a hyperproliferative skin disease, such as psoriasis. There is no teaching or suggestion that this active ingredient of Green would function as an antifungal agent for treating fingernail and toenail fungus. While Green teaches the possibility of adding an antimicrobial agent to its formulation, Green provides no teaching or suggestion that the antimicrobial agent should have antifungal properties for treating fingernail or toenail fungus. A person having ordinary skill in the art would not have been motivated to add an antifungal agent to Green's formulation for treating psoriasis by the statement "[t]he compositions ... may also contain other active ingredients such as antimicrobial agents, particularly antibiotics..." in view of the obvious absence of any suggestion of a need to kill fungus or of the particular suggestion of using an antifungal agent.

An antifungal agent, as claimed by Applicant, is not specifically disclosed by Green. Further, Green provides no motivation to add an antifungal agent to its formulation, as it is treating psoriasis. One of ordinary skill in the art would not know to treat a person's nail merely by Green's teaching of treating diseases of the skin. In fact, Green's formulation would not work

to treat one's nails even if an antifungal agent was added to it because it does not have a dual component penetration system of calcium hydroxide and sodium hydroxide.

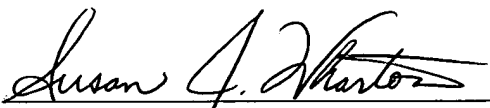
Antimicrobial agents include a broad spectrum of substances such as compounds that kill bacteria, fungi, or viruses. Within this species, Green only mentions antibiotics, which kill bacteria. Green provides no particular suggestion of using an antifungal agent. Thus, the mere mention of optionally adding antimicrobial agents, which cover a large genus of compounds, does not make a formulation containing a particular unnamed species within that genus, namely an antifungal agent, obvious, especially when the species is used in a different formulation for an entirely different application. See In re Jones, 958 F.2d 347, 350 (Fed. Cir. 1992), (Cited reference discloses "the potentially infinite genus of substituted ammonium salts of dicamba, and lists several such salts", but the salt claimed by the Applicant is not specifically disclosed. The Court reasoned that the claimed salt was not sufficiently similar in structure to those specifically disclosed in the cited reference as to render it *prima facie* obvious.) Green provides no teaching or suggestion that an antifungal agent placed in a calcium hydroxide and sodium hydroxide system would be effective at treating fingernail and toenail fungus.

Corning Glass Works v. Sumitomo Electric U.S.A. Inc., 9 U.S.P.Q. 2d 1962, 1970 (Fed. Cir. 1989) is also analogous to the present situation. In Corning Glass Works, defendant Sumitomo argued "that the use of the term 'dopant' in the Japanese publication, together with a listing of polyvalent metal oxide dopants, 'does not exclude germania.'" The Court reasoned that "[u]nder Sumitomo's theory, a claim to a genus would inherently disclose all species." The Court went on to state "[w]e find Sumitomo's argument wholly meritless whether considered under section 102(b) or under 35 U.S.C. §103...." For these reasons, Applicant submits that the pending claims are not anticipated or made obvious by Green.

II. CONCLUSION

In view of the foregoing remarks, it is respectfully submitted that the claims are now in condition for allowance and eventual issuance. Such action is respectfully requested. Should the Examiner have any further questions or comments which need be addressed in order to obtain allowance, please contact the undersigned attorney at the number listed below.

Respectfully submitted,

By: 
Susan J. Wharton, Reg. No. 41,524
STINSON MORRISON HECKER LLP
1201 Walnut, Suite 2800
Kansas City, MO 64106-2150
Telephone: (816) 842-8600
Facsimile: (816) 691-3495